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File: USPT

May 5, 1992

US-PAT-NO: 5110583

DOCUMENT-IDENTIFIER: US 5110583 A

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the location  
musical oil*

TITLE: Peroxy acids composition for oral treatment

DATE-ISSUED: May 5, 1992

## INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Sampathkumar; Padmini	Fairfield	OH		

US-CL-CURRENT: 424/48; 424/464, 424/49, 424/53, 514/714, 514/835

## CLAIMS:

What is claimed is:

## 1. A chewing gum composition comprising:

(a) from about 1.times.10.sup.-4 mole to about 2.5.times.10.sup.-3 mole per piece of gum of a monoperphthalate compound having the general structure: ##STR4## or its pharmaceutically-acceptable salts or esters, wherein M.sup.+n is a cation selected from the group consisting of an alkali metal, an alkaline earth metal, a non-toxic heavy metal, trimethylammonium and triethylammonium, and R is 1 or more substituents compatible with the peroxy acid functionality of the aromatic ring; and

(b) a chewing gum carrier comprising a gum base, flavoring and sweetening agents.

2. A chewing gum composition according to claim 1 containing from about 2.5.times.10.sup.-4 moles to about 1.75.times.10.sup.-3 moles of the monoperphthalate compound, based on the equivalents of peroxide units per compound.

3. A chewing gum composition according to claim 1 wherein the chewing gum carrier is buffered such that the oral cavity during use of the chewing gum has a pH of from about 5 to about 8.

4. A chewing gum composition according to claim 1 in which the monoperphthalate compound is magnesium monoperphthalate having the formula: ##STR5##.

## 5. A lozenge composition comprising:

(a) from about 1.times.10.sup.-4 mole to about 2.5.times.10.sup.-3 mole per lozenge of a monoperphthalate compound having the general structure: ##STR6## or its pharmaceutically-acceptable salts or esters, wherein M.sup.+n is a cation selected from the group consisting of an alkali metal, an alkaline earth metal, a non-toxic heavy metal, trimethylammonium and triethylammonium, and R is 1 or more substituents compatible with the peroxy acid functionality of the aromatic ring; and

(b) a lozenge carrier comprising a candy base, flavoring and sweetening agents.

6. A lozenge composition according to claim 5 containing from about  $2.5 \times 10^{-4}$  moles to about  $1.75 \times 10^{-3}$  moles of the monoperphthalate compound, based on the equivalents of peroxide units per compound.

7. A lozenge composition according to claim 5 wherein the lozenge carrier is buffered such that the oral cavity during use of the lozenge has a pH of from about 5 to about 8.

8. A lozenge composition according to claim 5 in which the monoperphthalate compound is magnesium monoperphthalate having the formula: ##STR7##

9. A sachet composition comprising:

(a) from about  $1 \times 10^{-4}$  mole to about  $2.5 \times 10^{-3}$  mole per sachet of a monoperphthalate compound having the general structure: ##STR8## or its pharmaceutically-acceptable salts or esters, wherein  $M^{+n}$  is a cation selected from the group consisting of an alkali metal, an alkaline earth metal, a non-toxic heavy metal, trimethylammonium and triethylammonium, and R is 1 or more substituents compatible with the peroxy acid functionality of the aromatic ring; and

(b) a sachet carrier comprising a sachet bag, flavoring and sweetening agents.

10. A sachet composition according to claim 9 containing from about  $2.5 \times 10^{-4}$  moles to about  $1.75 \times 10^{-3}$  moles of the monoperphthalate compound, based on the equivalents of peroxide units per compound.

11. A sachet composition according to claim 9 wherein the sachet carrier is buffered such that the oral cavity during use of the sachet has a pH of from about 5 to about 8.

12. A sachet composition according to claim 9 in which the monoperphthalic acid compound is magnesium monoperphthalate having the formula: ##STR9##

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TITLE: Peroxy acids composition for oral treatment

Brief Summary Text (4):

Virtually all anaerobic infections arise endogenously. Anaerobic bacteria are a part of the normal flora of the skin. They also exist prevalently on all mucous membrane surfaces as indigenous flora. Given the proper circumstances and opportunity to penetrate tissues, anaerobes from the indigenous flora set up infections, such as gas gangrene, vulvovaginal abscess, chronic sinusitis, and Vincent's disease. While treatment with hyperbaric oxygen or hydrogen peroxide may be effective against certain anaerobe infections, there is a need for safe and effective methods of treating or preventing anaerobe infections generally.

Brief Summary Text (15):

U.S. Pat. No. 3,988,433, issued Oct. 26, 1976 to Benedict, and Great Britain Patent 1,477,691, issued Oct. 19, 1977 to Jones et al., disclose compositions which contain alkyl and aryl peroxy acids. These compositions are used to remove stains from teeth.

Brief Summary Text (23):

The present invention relates to a method of treating or preventing topically-treatable anaerobe infections, especially diseases of the oral cavity (e.g. periodontal disease), in humans or lower animals by topically applying to the tissue, especially the tissue of the oral cavity, of the human or lower animal, a safe and effective amount of a singlet oxygen generating organic peroxy acid compound. By "singlet oxygen generating organic peroxy acid compound" as used herein is meant an organic acyl peroxide compound (e.g., an organic molecule which has at least one --CO.sub.3 H substituent) by itself, or in combination with hydrogen peroxide, whose oxidative ability is inhibited by greater than about 30% by a well-known singlet oxygen quencher (e.g. tertiary aliphatic amines such as 1,4-diazabicyclo[2.2.2]octane ("DABCO")) when the quencher is added at the same molar concentration as the organic acyl peroxide in solution. This inhibition can be monitored in two ways: (a) by monitoring the oxidation by the organic peroxy acid compound of a reactive substrate such as 1,3-diphenylisobenzofuran in the presence and absence of equimolar amounts of the singlet oxygen quencher, especially DABCO; and (b) by monitoring the antibacterial activity towards anaerobic bacteria (especially *Fusobacterium* such as *F. nultceatum*) of the organic peroxy acid compound in the presence and absence of equimolar amounts of the singlet oxygen quencher, especially DABCO. Organic peroxy acid compounds whose activity, as monitored by (a) or (b) above are inhibited to an extent greater than about 30% by the singlet oxygen quencher (e.g., DABCO) are considered for the purposes of this invention to be singlet oxygen generating organic peroxy acid compounds.

Brief Summary Text (53):

The carriers of the present invention can include the usual and conventional components of toothpastes (including gels), mouth rinses, mouth sprays, chewing gums, lozenges, and sachets as more fully described hereinafter. Generally, however, the carriers are limited to materials which are free of hydroxyl groups and normally also to materials which do not contain reactive sites, such as for example amino, amido, iodo, bromo, and sulfhydryl groups, and unsaturated, imino, and thioether linkages when the composition of the present invention is to be stored for any appreciable period of time. Thus, it is preferred that the monoperphthalic acid

compound be substantially anhydrous until just prior to use, for example, preparing a mouth rinse solution just prior to use by dissolving substantially anhydrous concentrate of monoperphthalic acid compound in water to the necessary concentration for use in the method of treatment of the present invention.

Detailed Description Paragraph Table (2):

triacetin balance Composition A magnesium monoperphthalate 5%  
balance Composition B magnesium monoperphthalate 2% mineral oil (SSF-60)  
balance Composition C magnesium monoperphthalate 10% menthyl acetate and menthene  
(1:1) 2% sodium alkyl (C.sub.10 -C.sub.12) sulfate 4% diethylether of polyethylene  
glycol (M.W. 1000) balance Composition D Component I: magnesium monoperphthalate 10%  
potassium polyethoxylated (4) 4% coconut fatty alcohol sulfate methyl laurate  
balance Component II: dicalcium orthophosphate 40% eucalyptol 2% phosphate buffer 3%  
NaF 0.5% color 0.1% methyl laurate balance \_\_\_\_\_